NOV - 2 2004

K042339

11. 510(K) Summary

NEOBIOTECH. Co.Ltd.
510(K) Premarket Notification
NEOPLANT Implant System 510(K) Summary

510(K) SUMMARY AND CERTIFICATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

11-1. Submitter	NEOBIOTECH. Co.Ltd. 8th. Floor Jeongkok B/D, 44-25 Yeou-Ieudong, Youngdeungpo-Gu, Seoul city, South Korea
11-2. Contact Person	Dae K Chang 9778 Katella Ave. Ste.215, Anaheim, CA 92804 Phone: 714-537-0600 Fax: 714-537-0601
11-3. Date Prepared	August 25, 2004
11-4. Device Name	NEOPLANT IMPLANT SYSTEM
11-5. Classification Name	Endosseous Dental Implant System
11-6. Device Classification	Class III Dental Devices panel 21 CFR ξ 872.3640 Regulation Number: 872.3640
1-7. Predicate Devices	3i Dental Implants (K86063, K874590, K950204, K955428)

11-8. Performance

K042359

Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

11-9. Device Description

NEOBIOTECH Internal Hex Implant System(NEOPLANT) consists of two-stage, root-form tapered and straight walled threaded dental implant and associated abutment system, which provide the clinical with Screw-Retained(UCLA, Cement-on Crown), and overdenture Snap Abutments. The System also includes surgical and restorative instrumentation: twist drills, surgical taps, surgical depth probe, depth gauge, abutment drivers, ratch-type drivers, open end wrench, and hand-piece adapters. NEOBIOTECH implant system(NEOPLANT) is available with a S.L.A. roughened surface. All implants have an internal hexagon as a connection and as an anti-rotational feature for the prosthetics.

11-10. PACKING/LABELING/PRODUCT INFORMATION

NEOBIOTECH Internal Hex Implant System (NEOPLANT) will be packaged.

11-11. Intended Use

NEOBIOTECH Internal Hex Implant System(NEOPLANT) is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

11-12. Substantial Equivalence Comparison

NEOBIOTECH Internal Hex Implant System(NEOPLANT) and the predicate implants share a substantially equivalent intended use. The 3i Dental Implants.(K86063, K874590, K950204, K955428) The screw –Vent and NEOBIOTECH Implant system(NEOPLANT) are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with roughened surfaces. The subject and predicate devices are similar in size and materials. All three system offers abutment systems for cement-retained, screw-retained and overdenture restorations as well as associated accessories and instruments. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the Implant system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2004

NEOBIOTECH Company Limited
C/O Mr. Dae-Kyu Chang
9778 Katella Avenue Suite 215,
Anaheim, California 92804

Re: K042339
Trade/Device Name: NEOPLANT IMPLANT SYSTEM
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: August 25, 2004
Received: September 7, 2004

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (If known): K042339

Device Name : NEOPLANT IMPLANT SYSTEM

Intended use/ Indications for Use:

NEOPLANT Internal Hex Implant system is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

510(k) Number: _____

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED

Rx ✓

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042339